**Annual Report**

Failure to submit an annual report may result in the termination of a DMF.

See the next page for the template. Information to be filled in, including notes about that information, is in brackets.

Date: [Enter the date of this submission]

DMF #: [Enter the DMF number]

Holder: [Enter the DMF holder’s name]

Subject (Title): [Enter the subject (title) of the DMF as it appears on the DMF List, available on the DMF web site at<https://www.fda.gov/drugs/forms-submission-requirements/drug-master-files-dmfs>]

Submission Type: Annual Report

Statement of Commitment: [For agent-submitted annual reports, the following statement of commitment, signed by the DMF holder, should be included in this letter.\* For holder-submitted annual reports, it should be included either in this letter or separately in eCTD section 1.2. If included in eCTD section 1.2, mention that here (e.g., “See eCTD section 1.2 for statement of commitment”).]

[DMF HOLDER] states that [DMF NUMBER] is current and [DMF HOLDER] will comply with the statements made within it. [DMF HOLDER] will notify FDA through an amendment to [DMF NUMBER] of any addition, change, or deletion of information in the DMF. [DMF HOLDER] will also notify [AUTHORIZED PARTY] in writing that an addition, change, or deletion of information has been made to the DMF as required by 21 CFR 314.420(c).

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature of DMF holder

[\* DMF holders should not delegate authority to agents to refer to the statement of commitment in the eCTD as current when submitting annual reports. Only DMF holders may refer to the statement of commitment in the eCTD.]

Dear DMF staff:

[Provide the following information:]

**Administrative Information**

[Provide a statement that the administrative information in eCTD section 1.3 is up-to-date.]

**Amendments**

[List the dates of any amendments submitted that report changes since the last annual report or the original DMF filing date, whichever is most recent.

OR

Provide a statement that no amendments have been submitted since the last annual report or the original DMF filing date, whichever is most recent.]

**Authorized Parties**

[Provide a statement that the list of authorized parties in eCTD section 1.4.3 is up-to-date.

OR

Provide a statement that there are no authorized parties for the DMF.]

**Authorizations Withdrawn**

[Provide a list of all parties whose authorization has been withdrawn and the dates of withdrawal.]

Sincerely,

[Signature of responsible official]

[Name of responsible official]

[Responsible official’s title]

[Responsible official’s company (i.e., DMF holder or agent)]

[Responsible official’s telephone number]

[Responsible official’s fax number]

[Responsible official’s email address]